JAN 1 3 2003

SECTION 10

510(k) SUMMARY K023464

This 510(k) summary of safety and effectiveness for the modification in the Indications for Use for the Viridis Twin laser is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: Quantel Medical

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Contact Person: Mr. Jean Abascal
Regulatory Affairs Manager

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Preparation Date: September 2002
(of the Summary)

Device Name: Viridis Twin Ophthalmic Photocoagulator

Common Name: Ophthalmic Laser, frequency doubled Nd:YAG (532 nm) laser
Laser Surgical Instrument, frequency doubled Nd:YAG (532 nm) laser
Ophthalmic Laser, 810 nm diode laser
Laser Surgical Instrument; 810 nm diode laser

Classification Name: Ophthalmic laser (see 21 CFR 886.4390)
Laser surgical instrument (see: 21 CFR 878.4810).

Product Code: HQF; Panel: 86
Product Code: GEX; Panel: 79

Predicate devices: Viridis Laser (K960867); Novus Verdi Delivery Systems (K991258) -and the Viridis laser

IRIS Medical OcuLight SL/SLx (K020374); Nidek DC-3300 (K013760)
The predicate lasers utilize several delivery systems, including slit lamp adapters, biomicroscopes, endoprobes, and indirect ophthalmoscopes to deliver the laser energy to the treatment sites.

The delivery systems used with the Viridis Twin Ophthalmic Photocoagulator are the same as or similar to delivery systems supplied with or used with other ophthalmic photocoagulators operating at 532 nm and/or 810 nm. These devices are independently marketed by their respective manufacturers which are responsible for complying with regulatory and marketing requirements. The cited models are compatible for use with the Viridis Twin Ophthalmic Photocoagulator.

Device description: The Viridis Twin Ophthalmic Photocoagulator is a combination system consisting of a Nd:YAG frequency doubled laser which emits a beam of coherent light at 532 nm and a diode laser which emits a beam of coherent light 810 microns. The treatment beam is selected by the user, the delivery system is attached to the appropriate laser aperture, and the energy is delivered to the treatment site(s) via delivery systems/devices.

Indications: The Quantel Viridis Twin Ophthalmic Photocoagulator is indicated for the photocoagulation or ablation of pigmented tissue within the eye.

The 532 nm wavelength is indicated for use for:

retinal photocoagulation
proliferative diabetic retinopathy,
macular degeneration, and
retinal detachment.
peripheral photocoagulation
proliferative diabetic retinopathy,
macular degeneration, and
retinal detachment.
endophotocoagulation (EPCP)
intraocular photocoagulation as an adjunct in vitrectomy surgery,
complicated rhegmatogeous,
tractional retinal detachments,
proliferative vitreoretinopathy,
proliferative diabetic retinopathy,
retinopathy, and
retinal vascular tumors.

The 810 nm wavelength is indicated for use for:

photocoagulation or ablation of pigmented tissue within the eye,
transscleral ciliary body ablation (treatment is reserved for patients with chronic glaucoma and those not responding to conventional treatments),
limited and pan-retinal photocoagulation,
transpupillary photocoagulation,

endophotocoagulation,
treatment of complicated rhegmatogeous, tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy, macular degeneration, peripheral photocoagulation (recumbent patients),
transpupillary photocoagulation of choriodal neovasculature, and
age-related macular degeneration (AMD) treatments.

Performance Data: None required.

CONCLUSION: Based on the information in this notification Quantel Medical concludes that the Viridis Twin Ophthalmic Photocoagulator is substantially equivalent to the cited legally marketed predicates. Information regarding delivery systems which may be used with the laser is supplied by Quantel Medical; the individual devices or systems are marketed by their respective manufacturers who have the responsibility for complying with applicable regulations and marketing requirements.

Revised: January 2003

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 13 2003

Quantel Medical
c/o Roger W. Barnes
342 Sunset Bay Road
Hot Springs, Arkansas 71913

Re: K023464
Trade/Device Name: Viridis Twin Ophthalmic Photocoagulator
Regulation Number: 886.4390
Regulation Name: Laser surgical instrument
Regulatory Class: Class II
Product Code: GEX
Dated: October 9, 2002
Received: October 15, 2002

Dear Mr. Barnes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 7

INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K023464

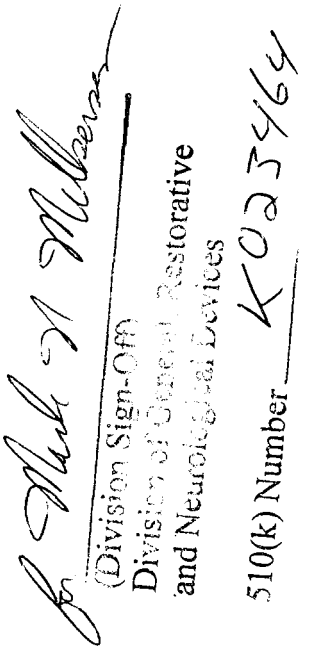
Device Name: Viridis Twin laser

Indications for Use Statement:

The Viridis Twin laser is indicated for the photocoagulation or ablation of pigmented tissue within the eye.

The 532 nm wavelength is indicated for use for:

retinal photocoagulation
proliferative diabetic retinopathy,
macular degeneration, and
retinal detachment.
peripheral photocoagulation
proliferative diabetic retinopathy,
macular degeneration, and
retinal detachment.
endophotocoagulation (EPCP)
intraocular photocoagulation as an adjunct in vitrectomy surgery,
complicated rhegmatogeous,
tractional retinal detachments,
proliferative vitreoretinopathy,
proliferative diabetic retinopathy,
retinopathy, and
retinal vascular tumors.



The 810 nm wavelength is indicated for use for:

photocoagulation or ablation of pigmented tissue within the eye,
transscleral ciliary body ablation (treatment is reserved for patients with chronic glaucoma and those not responding to conventional treatments),

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation

Prescription Use ✓ OR Over-The Counter Use
(Per 21 CFR 801.109)

limited and pan-retinal photocoagulation,
transpupillary photocoagulation,
endophotocoagulation,
treatment of complicated rhegmatogeous, tractional retinal detachments, proliferative vitreoretinopathy, proliferative diabetic retinopathy, macular degeneration, peripheral photocoagulation (recumbent patients),
transpupillary photocoagulation of choriodal neovasculature, and
age-related macular degeneration (AMD) treatments.

revised: January 2003